## IN THE DRAWINGS

Please amend Fig 4B, as indicated in red in the attached sheets of drawings labeled as "Marked up Versions". The changes indicated in the marked up versions have been incorporated into the claim drawing sheet showing Fig 4B and properly labeled as a "REPLACEMENT SHEET"

New Formal drawings incorporating the changes made therein will be submitted upon receiving an indication from the examiner that the changes to the drawings are acceptable.

## REMARKS

### I. OVERVIEW

In the Official Action, the Examiner raised a host of technical objections to the claims based on 35 U.S.C. Sections 101 and 112. Additionally, the Examiner rejected some of the claims on substantive grounds based on 35 U.S.C. Section 103. To support these substantive rejections, the Examiner cited previously cited art, along with two newly found references including McAuley U.S. Patent Application Publication 2003/0094178, and Barrett, U.S. Patent No. 6,412,488.

With this Response, the Applicants have amended the Specification, the Claims and the Drawings, were necessary, to overcome the Examiner's technical objections. Additionally, the Applicants have amended the claims where necessary, to point out those features that patentably distinguish the Applicants' invention from the art of record.

As set forth in more detail below, the changes made to various parts of the Specification are believed to overcome the technical objections. It is believed that the claims of the application are now in condition for allowance, as none of the art of record discloses or suggests the Applicants' claimed invention.

### II. REJECTION UNDER SECTION 101

The Examiner first rejected the claims under Section 101. In particular, the Examiner believed that several of the claims were directed to non-statutory matter such as "a patient having a forehead, a mouth and a nose having a naris".

In this regard, the Applicants would like the Examiner to first note that no where in the claims, were the Applicants attempting to claim the non-statutory subject matter of a human being, or the body parts of a human being, such as a forehead, mouth and a nose having a naris. Rather, these body parts were inserted into the claim, to help clarify features relating to the apparatus of the claim, such as the positioning of the mask, that covers the nose but not the mouth; the naris of the nose into which the flexible cannula extends; and the forehead, over which the exhaust tube extends in certain of the claims.

In placing these body parts in the preamble of the claims, the Applicants were attempting to provide an appropriate antecedent basis for later recitations in the claims that related to the positioning of the various parts of the invention relative to the body parts mentioned. As such, the Applicants believe that these recitations were not objectionable under Section 101.

In reviewing the Examiner's rejection, it appears the Examiner's primary objections related to the use of the body parts within the preamble of certain of the claims. To help address the Examiner's concerns, the Applicants have, in this Amendment, removed the body part recitations from the preamble of the claim, but has maintained them in other places in the claims.

The Applicants submit that this is perfectly acceptable within the rules of practice, and does not run a foul of Section 101. To support the Applicants' belief, the Applicants direct the Examiner's attention to Exhibit A. Exhibit A comprises samples of issued patents having claims that include recitations of body parts. These claims are pertinent as, just in the present invention, it is believed by the Applicants that the patents listed in Exhibit A do not make any attempt to claim the body parts listed in the claims, but rather, recite the presence of certain body parts as locators, to better describe particular parts of the various devices being claimed.

Exhibit A is not an inclusive list. It does not include all of the patents that recite a body part within a claim. The Applicants believe that such a list would be too extensive to include, for in the Applicants' limited search, they found 1,338 issued patents that included both of the terms "nose" and "mouth" within a claim.

Turning now to the patents contained with Exhibit A, it will also be noted that many of the patents appeared to have been examined by the Examiner's art unit, as the Examiner's supervisor, Henry Bennett, is listed as a primary Examiner on several of the patents shown in Exhibit A.

For the reasons set forth above, the Applicants submit that the Examiner's objections under Section 101 have either been rendered moot by the amendment made to the claims, or alternately, were rendered moot due to the impropriety of the rejections.

## III. REJECTIONS UNDER SECTION 112

In the Official Action, the Examiner objected to Claims 1, 21, 30, 34-37 and 39 under Section 112.

In particular, the Examiner believes that the claims contain subject matter that was not described in the Specification in such a way as to reasonably convey to one skilled in the art that the inventor had possession of the claimed invention. The Examiner believes that no support exists for terms such as "flexible cannula", "middle portion", "a second flexible cannula", a "first cannula to resist a movement of the first cannula" [that was] moved by the user"; and "a second inspiratory port being sized for slideably receiving the second cannula... of the second cannula when not being moved by the user".

Contrary to the Examiner's assertion, the Applicants believe that all of the materials above are described within the Specification, and are contained within the Specification in a manner that would enable one reasonably skilled in the art to appreciate the presence of these elements.

In this regard, the Examiner's attention is first directed to lines 17-22 of page 24, and lines 1-13 of page 25. This section of the application (as amended by the instant Response) is set forth below.

> "The first and second nasal cannulas 180, 184 are generally flexible pieces of respiratory tubing used with anesthesia devices. The first nasal cannula 180 has a source end 179, ~~and~~ a patient end 181, and a middle portion 193 disposed between the source end 179 and the patient end 181. The second nasal cannula 184 has a source end 183, ~~and~~ a patient end 185, and a middle portion 195 disposed between the source end 183 and the patient end 185. The source end 179 of the first nasal cannula 180 is connected to the patient end 171 of the first patient connector 172 of the mask connector 170. The source end 183 of the second nasal cannula 184 is connected to the patient end 173 of the second patient connector 174 of the mask connector 170. The inspiratory gas coming from the first patient connector 172 of the mask connector 170 enters the source end 179 of the first nasal cannula 180 and exits through the patient end 181. The inspiratory gas coming from the second patient connector 174 of the mask connector 170 enters the source end 183 of the second nasal cannula 184 and exits through the patient end 185.
>
> The first and second nasal cannula 180, 184 extend through the first and second inspiratory gas ports 121, 122 of the anesthesia mask 112 such that the patient ends 181, 185 of the nasal cannulas 180, 184 are under the crown member 132. The first and second inspiratory gas ports 121, 122 can be sized to form a snug fit with the first and second nasal cannula 180, 184 such that the user can move the cannula 180, 184 to place the patient ends 181, 185 in a desired position within the crown member 132 for delivery of inspiratory gas to the patient.
>
> As best shown in Figs. 5B and 6B, the patient ends 181, 185 of the nasal cannulas 180, 184 extend through the gas inspiratory ports 121, 122 of the crown portion 132."[1]

[1] The underlining and strikeout show amendments made in this Response

Turning to the above excerpt from the application, you will notice that it first states that "the first and second nasal cannulas 180,184 are generally *flexible* pieces of respiratory tubing used with anesthesia devices" (emphasis added). This sentence clearly discloses the fact that the tubes are flexible.

The next two sentences recited, prior to editing, that the first nasal cannula had a source end 179 and a patient end 181. It also recited that the second nasal cannula 184 had a source end and a patient end 185.

With this amendment, the Applicants have also added that the first and second nasal cannulas include middle portions 193, 195 respectively, that are disposed between the source end and the patient end.

Although the term "middle portion" was not used *per se* in the application as originally filed, the Applicants submit that a middle portion is clearly disclosed.

Your attention is now directed to Exhibit B, that comprises an excerpt from the Merriam Webster Collegiate Dictionary (10th Edition), and more particularly, to the dictionary's definition of "middle". The dictionary defines middle as 2: being at neither extreme, and also defines it as 1: a middle part, point or position [and] 4: something intermediate between extremes.

In the instant context, the source end 179 and patient end 181 are the "extremes" of the first nasal cannula. It follows, therefore, that the middle portion 193 of the first cannula is that portion of the cannula 180 that is disposed between the two extremes of the cannula, namely, the source end 179 and the patient end 181.

The same logic applies with respect to the second nasal cannula 184.

Turning now to Fig. 4B, it will be noted that the first and second cannulas, 180 184 are clearly shown as having middle portions 193, 195 respectively, that exist between their respective ends. As the disclosure of an application includes all of the subject matter within the originally filed application, including the Specification, Claims, Abstract and Drawings, the Applicants submit that a middle portion was, and always has been shown in the application, and as such is, (and was when filed), disclosed in a manner to enable one skilled in the art to understand the invention.

The additional clauses added by the Applicants relating to the middle portion add no new matter, but rather, do little more than commit to prose that which had already been disclosed in picture and logic.

In summary, the Applicant believes that the middle portion, while always disclosed explicitly, is now, with the amendment, disclosed more explicitly.

Turning back to the same section, the Applicant submits that the quoted passages set forth above also clearly disclosed the presence of a second cannula, (Claim 35), and a first and second flexible cannula (Claim 36).

The Examiner also believes that in Claims 36 and 37, terms such as "first cannula to resist movement of the ... moved by the user ... a middle portion, second inspiratory port being sized for slideably receiving the second cannula ... of the second cannula not being moved by the user. ," were not fully disclosed in the Specification.

Contrary to the Examiner's belief, the above recitations are fully supported and disclosed in the Specification.

The Examiner's attention is directed to the excerpt below taken from the application, at

page 22, lines 20-22, and page 23, lines 1-6.

> The first and second inspiratory gas ports 121, 122 are generally circular openings in the crown member 132 that are sized for snugly, but slideably receiving the inspiratory gas line 120 so that the inspiratory gas line can extend there through to deliver inspiratory gases directly to the patient's nose within the anesthesia face mask 112. Fig. 4B shows an inspiratory gas line 120 which includes a source line 152; a line splitter 156; first and second intermediate lines 160, 164; a slide member 162, a mask connector 170 and first and second nasal cannula 180, 184. The source line 152 is a generally cylindrical gas line used in anesthesia devices that includes a source end 151 and a patient end 153. The source end 151 is connected to an inspiration gas source 150, and the patient end 153 is connected to the line splitter 156.

The excerpt above clearly states that the first and second inspiratory gas ports 121, 122 are sized for *snugly but slidably* receiving the inspiratory gas line 120, so that the inspiratory gas line can extend therethrough.

The Examiner's attention is now directed to the excerpt below, that is taken from the Specification at page 25, lines 6-15.

> The first and second nasal cannula 180, 184 extend through the first and second inspiratory gas ports 121, 122 of the anesthesia mask 112 such that the patient ends 181, 185 of the nasal cannulas 180, 184 are under the crown member 132. The first and second inspiratory gas ports 121, 122 can be sized to form a snug fit with the first and second nasal cannula 180, 184 such that the user can move the cannula 180, 184 to place the patient ends 181, 185 in a desired position within the crown member 132 for delivery of inspiratory gas to the patient. As best shown in Figs. 5B and 6B, the patient ends 181, 185 of the nasal cannulas 180, 184 extend through the gas inspiratory ports 121, 122 of the crown portion 132. As the patient end 181 185 of the nasal cannulas 180, 184 within the nares N of

> the nose Z of the patient P, the anesthesia gas is deposited directly into the nares N for inhalation by the patient.

This section clearly states that the first and second nasal cannula 180, 184 extend through the inspiratory gas ports 121, 122, and that the inspiratory gas ports are sized to form a snug fit with the first and second cannulas such that the user can move the cannula to place the patient end in a desired position within a crown member.

The "snug but slidable" description of the size relationship between the gas ports and cannula clearly discloses that the cannula and gas ports are sized relative to each other, to have a "loose" enough fit so that the cannulas can be slid within the gas port to change the amount of length of the cannula that is within the dome of the mask; while still retaining a "snug" enough fit between the cannula and the gas port so that the cannula and the gas port will tend to retain their relative positions within the gas port in the absence of a force (such as that exerted by the user) that serves to either slide the cannulas in the gas port, to either increase or decrease the length of the cannula disposed within the interior of the dome portion of the face mask.
As such, the Applicants submit that they have complied fully with the written description requirement, as all of the materials recited in the claims are clearly disclosed within the Specification.

The Examiner later suggests that in paragraph 6 of the Official Action, that the middle portion is not disclosed in the original disclosure. For the reasons set forth above in connection with the Applicants' disclosure of what constitutes a "middle portion", the Applicants submit that a "middle portion" is fully disclosed now in the amended Specification, and was fully disclosed in the originally filed application.

## IV. THE SUBSTANTIVE REJECTIONS

*A. Overview of the Examiner's rejections made in the 25 January 2006 Official Action.*

In the Official Action, the Examiner rejected all of the claims under Section 103. To support the rejection, the Examiner employed a combination of references for each rejection.

The art relied on by the Examiner included references such as Blasdell, U.S. Patent No. 5,419,317; Schauweker, U.S. Patent No. 2,462,005; Kwok, U.S. Patent No. 6,112, 746; Vanuch, U.S. Patent No. 5,243,708 and Muto, U.S. Patent No. 4,454,880.

The above mentioned references were all originally used to reject the claims in the first Official Action.

As stated at the interview, none of the Blasdell, Schauweker, Kwok, Vanuch or Muto disclosed or suggested the use of an inspiratory gas line for delivering inspiratory gases, wherein the inspiratory gas line of a patient end that was configured for insertion into the naris.

In the rejections, the Examiner also cited additional references not previously seen, namely McAuley, U.S. Patent Application No. 2003/0094178, and Barnett, U.S. Patent No. 6,412,488.

McAuley was cited primarily because of its alleged teaching of an inspiratory gas provided within each nostril of a patient through a nasal cannula. Barnett was recited primary because of its alleged teaching of a nasal face mask assembly having an exhaust tube in communication with the mask at an elbow connection, wherein the exhaust tube extended over the forehead of the patient.

*B. The Applicants' Invention and the Claims As Amended.*

As discussed in the Response to the last Official Action, one of the features of the Applicants' invention is that it includes a flexible cannula having an outside portion disposed outside the dome, a patient end inserted into the naris of a patient, and the middle portion that is adjustably positionable with respect to the face mask, to permit the user to adjust the position of the cannula. This position can be adjusted in a manner that increases or decreases the length (amount) of the cannula within the dome portion.

By enabling the user to vary the length of the cannula within the dome portion, he can adjust the length of the cannula to fit noses of different sizes. Further, the flexible nature of the cannulas, when coupled with their "snug but slidable" engagement with the gas ports allows the first and second cannulas to be independently adjustable with respect to each other in those embodiments employing a first and a second cannula. This independent adjustability further enhances the medical practitioner's ability to vary the position fo the two cannulas to better fit the particular patient, and also better enables the practitioner to position the first and second cannulas independently of each other.

Additionally, the flexibility of the cannula permits the user to manipulate the position of the cannula so that the user (usually a medical or dental practitioner) can better adjust the lateral position of a cannula to better fit the nose of the patient into which the cannula is being inserted.

As discussed in the last Official Action, noses vary in length, width and other factors. Importantly, noses vary in the width of the columella that separates the nose into two nostrils (naris). Because the columella of patients differ widely, the Applicants have found that it is very helpful to be able to adjust the relative width and separation of the cannulas inserted into the nostril to ensure that the nostril-engaging patient ends of the inspiratory port are properly

positioned within the nostril. This variable positioning cannot be accomplished with either the Fisher device that was discussed in the last Official Action, or with the devices shown in the McAuley or Barnett references disclosed in this Official Action.

Additionally, the Applicants' arrangement also permits the length of the cannula within the interior of the face mask to be varied. The Applicants' design enables the practitioner to insert a relatively long portion of the cannula interiorly of the face mask to ensure that the cannula is inserted deeply enough within the naris of the patient to help ensure that gas flowing from the cannula is received within the body of the patient. Alternately, the practitioner can pull the cannula out to reduce the length of the cannula within the dome portion, so that only a short length of the cannula is contained within the interior of the mask. A shorter length of cannula placed inside the mask may be appropriate if the patient has a large or long nose, that is placed close to the dome. In such a large-nosed patient, only a short length of cannula is necessary to have the cannula inserted at a proper depth within the naris. The "axial variability" of the Applicants' invention is not possible with the configurations shown in the prior art.

Another feature of the Applicants' invention is that it includes an exhaust port, elbow and exhaust tube arrangement that allows the exhaust tube it to pass over the forehead of a patient, rather than along side the patient. The advantage obtained by this feature is that masks having "side loading" tubes tend to be ergonomically disadvantageous to the practitioner operating on the patient.

Because many procedures are rather lengthy, practitioners (especially dentists, and oral surgeons) prefer to sit while performing a procedure on the patient. The side hanging hoses on masks, such as those shown in the prior art, force the oral surgeon to place herself in a position

where she can work on the patient while not interfering with the hoses. This causes the oral surgeon to position herself further away from the patient than she would prefer.

By contrast, one embodiment of the Applicants' invention employs an exhaust line that hangs over the forehead of the patient and over the patient's head, and then leads back to the anesthesia device. Through the Applicants' configuration, the oral surgeon does not need to "work around" the side hanging tubes. As such, the oral surgeon can get closer to the patient, and assume a more ergonomically correct position while operating on the patient.

*C. The Newly Cited Art*

In the prior response, it was pointed out that the prior cited references, including Fischer, U.S. Patent No. 4,248, 218; and Brekke et al,, U.S. Patent No. 4,151,843 did not disclose or suggest the applicant's invention, and that he applicant's claims were patentably distinguishable over these references.

As discussed above, none of the art cited in *this* Official Action, that was cited in previous Official Actions discloses or suggests the Applicants' flexible and adjustably positionable cannula, nor does the prior cited art disclose or suggest the Applicants' arrangement wherein the exhaust elbow and exhaust line arrangement is positioned to extend over the forehead of a patient. the newly cited prior art does not disclose or suggest these features either.

1. McAuley U.S. Patent Publication No. 2003/0094178

The McAuley reference actually shows two very distinct devices. The device shown in Figs. 2 and 7 appears to comprise a pair of nasal tubes 32, 33 coupled together by a "Y"

connector 31. The McAuley nasal tube device 30 appears to be a stand alone device, that is used by itself, rather than being used with a mask. Nothing in the McAuley patent discloses that the device shown in Fig. 2 is useable in connection with a mask.

The second embodiment of McAuley's device is best shown in Figs. 11-16. Turning now to Fig. 11, one of the single tubes 65 is used. Tube 65 terminates at an end (close to the end of line 62). A mask 61 (referred to as a nasal sealing flap) is provided, and a pair of cannulas, 63, 64, extend through the mask.

As you will note from the drawings, the length of the cannula 63, 64 are rather short. Additionally, there is little length of cannula between the mask and the end of tube 60. It is also note worthy that the cannula 63, 64 are designed for "inspiratory gas" to be delivered to a patient, and that there is no feature in McAuley's mask that would provide any evacuation of gas.

Most importantly, McAuley's cannula 63, 64 are not adjustably positionable with respect to the mask. In this regard, the Examiner's attention is directed to paragraph 59 of the McAuley reference that is shown at page 4, col. 2. McAuley states:

> "The nasal device comprises the nasal sealing flap [mask] 61 connected by appropriate means to a nasal member 62 that terminates in at least one nasal cannula, although in the preferred form two cannulae 63, 64 are provided, one for each of the patient's nares. The *flap 61 and cannulae 63,64 may be integrally formed or the flap 61 may be attached about the cannulae 63, 64 (by appropriate means, such as gluing) after the cannulae have been formed. Furthermore, the cannulae 63, 64, flap 61 and nasal member 62 may all be integrally formed by injection molding or the like methods*. The cannulae 63, 64 extend through the proximate end of the flap 61, so that in use, upon placing the flap about the patient's nose the cannulae extend into the nasal cavities of the patient's nose. The other end of the nasal member 62 is connected, again by appropriate fixing means, such as by friction fit, snap fit, gluing, welding, threading or the like, to a nasal tube 65." (Emphasis added)

As will be appreciated, the integral molding of the cannulae 62, 63 and mask 61; or alternately, the gluing of the cannulae 63, 64 to the mask 61, in McAuley will fixedly position the cannulae 62, 63 with respect to the mask 61. As such, the cannulae cannot be slid with respect to the mask, to make the portion of the cannulae inside the mask either longer or shorter, to adjust to patients having noses of different sizes. Additionally, from the length of the cannulae shown in the drawings, the cannulae 63, 64 do not appear long enough to provide much lateral adjustability.

In summary, nothing in McAuley discloses or suggests providing an adjustably positionable cannula in connection with the face mask system, as recited in Applicants' claims. Nor does anything in McAuley disclose or suggest providing a mask system having an exhaust valve, wherein the exhaust valve is placed over the forehead of the patient, that is also recited in the Applicants' claims.

2. Barnett U.S. Patent No. 6,412,488

The Barnett reference was cited primarily against the feature recited in Applicants' claims that relates to the exhaust tube being positioned to extend over the forehead of the patient. (See Applicants' Claims 24 and 38). Turning now to Barnett at Fig. 1A, it will be noticed that Barnett shows a mask that appears to have a soft face-engaging portion 32, and gas port 76 that forms an elbow, and terminates the conduit receiver 36, that can be attached to a tube of some sort.

Barnett describes the area shown as 58 as being the upper portion of the face mask. Therefore, it appears that the conduit 36 may extend generally parallel to the nose, and would open upwardly to a position adjacent the forehead.

However, an important distinction between Barnett and the Applicants' claimed invention exists. This distinction is the conduit 36 is described in Barnett as being an *inspiratory* conduit, rather than an *evacuation or exhaust* conduit. As such, Barnett does not disclose or suggest the use of an exhaust or evacuation conduit that is positionable to extend over the forehead. Additionally, Barnett does not disclose or suggest the use of flexible cannula, as no cannulas that are insertable into the naris of a patient are shown or suggested anywhere within the Barnett device.

## V. AMENDMENTS TO THE CLAIMS

In this Response, the Applicants have amended their claims to more clearly recite those differences, described above, that patentably distinguish the Applicants' invention from the art of record.

Turning now to Claim 1, it will be noted that it has been amended to now recite that the dome [of the face mask] includes a gas port, and that the gas port of the face mask is sized to slideably receive the flexible cannula for permitting the user to move the cannula relative to the face mask and gas port to enable a user to place an end of the flexible cannula in a desired position within the naris of the patient.

Claim 21 has been amended similarly to Claim 1 and includes the recitation described above in connection with Claim 1.

As alluded to above, this feature is neither disclosed or suggested in any of the art of record, as McAuley neither discloses or suggests such an adjustably positionable cannula that is placeable within the naris of a patient. Certainly, the fixedly position cannula of McAuley cannot

disclosure or suggest it.

The Examiner's attention is next directed to Claim 24. Claim 24 recites the combination of a face mask, an exhaust port, an inspiratory port, an inspiratory gas line, an elbow, and an *exhaust line*, wherein the exhaust line is positioned by the elbow to extend over the forehead of a patient. As discussed above, Barnett does not disclose or suggest such a device. To the contrary, Barnett discloses the use of an inspiratory line that extends over the forehead, rather than an exhaust line that is claimed by the Applicants.

The Examiner's attention is next directed to Claim 25. Claim 25 has been amended to include a recitation similar to that discussed above in connection with Claim 1. Even though the Applicants believe that Claim 25 is allowable for no other reason than its dependency from allowable Claim 24, the Applicants submit that Claim 25, on its own, includes additional recitations that render it patentably distinguishable from the art of record, regardless of whether the Examiner would find Claim 24 to be allowable.

The Examiner's attention is next directed to Claim 30. Claim 30 has been amended to recite that the middle portion of the flexible cannula is slideably but snugly received in the inspiratory port to extend through the dome portion.

This snug but slideable connection between the cannula and the dome portion gives the flexible cannula and the user the ability to adjust the length of the cannula within the dome portion, to thereby enable the cannula to be positioned to better fit the patient, than a device wherein such adjustability was not achievable. Nowhere is this disclosed or suggested in the art of record, as the art cited by the Examiner, including McAuley and Fisher, that contain naris-insertable cannulas, do not disclose or suggest a nasal insertable cannula that is adjustably

positionable.

This "slideably but snugly" feature has also been added to Claim 36. Although Claim 36 is believed to be allowable based solely upon its dependency from allowable Claim 1, this additional recitation provides a further patentably distinguishing recitation that makes Claim 36 allowable, even if the Examiner were to find that Claim 1 (the claim from which it depends) is not patentable. This "slideable but snugly received" feature of the cannula is also incorporated into amended Claim 37.

The Examiner's attention is next directed to Claim 38. Claim 38 is similar to Claim 24, as both recite the presence of a face mask, inspiratory gas line, a vent, an exhaust port, an elbow, and an exhaust line, wherein the exhaust line is positioned by the elbow to extend over the forehead of the patient. For the same reasons as those discussed in connection with Claim 24, the Applicants believe that Claim 38 is patentably distinguishable over the art of record.

Claim 39 depends from Claim 38, and includes a recitation relating to the device including a flexible cannula that is slideably but snugly received by, and extends through an inspiratory port in the face mask. Even if the Examiner were to believe that Claim 38 is not patentable, these features recited within Claim 39 patentably distinguish it from the art of record, and argue strongly for its allowance over the art of record.

The Examiner's attention is next directed to Claim 40, which depends from Claim 1. Claim 40 recites that the inspiratory gas port of the face mask is sized to slideably but snugly receive the flexible cannula relative to the face mask and gas port, to enable the user to adjust the length of the cannula within the inside air space so that the cannula is properly positioned within the naris of a patient. This feature amplifies the distinctions discussed above between the

Applicants' face mask and cannula arrangement and that disclosed by the prior art. Although the Applicants believe that Claim 40 is allowable by virtue of its dependency upon allowable Claim1, the Applicants also submit that Claim 40 is patentable in its own right, even if the Examiner were to find that Claim 1 was not patentable.

Finally, the Examiner's attention is directed to newly added Claim 41. Newly added Claim 41 recites that the device includes a face mask, an inspiratory gas line having a patient end portion, and a face mask. The patient end portion of the inspiratory gas line includes a source end, a patient end disposed within the dome portion and being configured for being received within the naris of a patient for delivering inspiratory gas to the naris of a patient. Additionally, the patient end portion includes a middle portion that extends through the dome portion, and has a length disposed within the dome portion, wherein the length of the middle portion disposed within the dome portion is variable by the user.

Nowhere is this variable length cannula and mask arrangement disclosed or suggested by any of the art of record.

In summary, the Applicants have amended their claims to recite those differences that help to further distinguish the Applicants' invention from the art of record. For the reasons set forth in connection with the Examiner's Section 112 rejections, all of the materials that have been added by this Amendment are clearly disclosed by the application, and were disclosed by the Applicants at the time of filing. As such, nothing within the claims adds anything to the claims that could be construed as comprising new matter.

## VI. SUMMARY

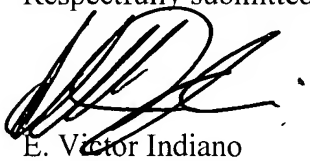
Applicants believe that the present application, as amended, is in condition for allowance. Re-examination and reconsideration, culminating in the allowance of all claims, in due course, is respectfully requested.

If the Examiner has any questions relating to this Amendment, or would like to discuss any issues about this case with the Applicants' Attorney, she is respectfully requested to contact the Applicants' Attorney, E. Victor Indiano, at (317) 822-0033, or via e-mail at Vic@IPLawIndiana.com.

## VII. REQUEST FOR EXTENSION OF TIME

If necessary, Applicants request that this Response be considered a request for an extension of time for a time appropriate for the response to be timely filed. Applicants request that any required fees needed beyond any submitted with this Response, be charged to the account of **E. Victor Indiano, Deposit Account Number 50-1590**.

Respectfully submitted,



E. Victor Indiano
Reg. No. 30,143

Enc: Marked up copy of Fig 4B and a replacement sheet of drawings containing Fig 4B and labeled as a "REPLACEMENT SHEET"

Exhibit A– Copies of issued patents showing the recitation of "body parts" within an allowed and issued claim.

Exhibit B– An excerpt from the Merriam-Webster New Collegiate dictionary defining "Middle"

cc: Kevin Burrow
Dennis Irlbeck
John Moenning
Thomas McGrail

W:\Word Processing\7432 - King Systems\46 - response to official action or 25 January 2006.wpd

# Merriam-Webster's Collegiate® Dictionary

## TENTH EDITION

Merriam-Webster, Incorporated
Springfield, Massachusetts, U.S.A.

**mi-cro-pro-ces-sor** \ˌmī-krō-ˈprä-ˌse-sər, -ˈprō-\ *n* (1970) : a computer processor contained on an integrated-circuit chip; *also* : such a processor with memory and associated circuits
**mi-cro-pro-gram** \ˈprō-ˌgram, -grəm\ *n* (1953) : a routine composed of microinstructions used in microprogramming
**mi-cro-pro-gram-ming** \-ˌgra-miŋ\ *n* (1953) : the use of routines stored in memory rather than specialized circuits to control a device (as a computer)
**mi-cro-pro-jec-tor** \-prə-ˈjek-tər\ *n* (1927) : a projector utilizing a compound microscope for projecting on a screen a greatly enlarged image of a microscopic object — **mi-cro-pro-jec-tion** \-ˈjek-shən\ *n*
**mi-cro-pub-lish-ing** \-ˈpə-bli-shiŋ\ *n* (1966) : publishing in microform — **mi-cro-pub-lish-er** \-bli-shər\ *n*
**mi-cro-pul-sa-tion** \-ˌpəl-ˈsā-shən\ *n* (1949) : a pulsation having a short period (a ~ of the earth's magnetic field with a period in the range from a fraction of a second to several hundred seconds)
**mi-cro-punc-ture** \-ˈpəŋ(k)-chər\ *n* (1948) : an extremely small puncture (as of a nephron); *also* : an act of making a micropuncture
**mi-cro-pyle** \ˈmī-krə-ˌpīl\ *n* [F, fr. *micr-* + Gk *pylē* gate] (1821) **1** : a minute opening in the integument of an ovule of a seed plant **2** : a differentiated area of surface in an egg through which a sperm enters — **mi-cro-py-lar** \ˌmī-krə-ˈpī-lər\ *adj*
**mi-cro-quake** \ˈmī-krō-ˌkwāk\ *n* (1967) : MICROEARTHQUAKE
**mi-cro-ra-di-og-ra-phy** \ˌmī-krō-ˌrā-dē-ˈä-grə-fē\ *n* (1913) : radiography in which an X-ray photograph is prepared showing minute internal structure — **mi-cro-ra-dio-graph** \-ˈrā-dē-ə-ˌgraf\ *n* — **mi-cro-ra-dio-graph-ic** \-ˌrā-dē-ə-ˈgra-fik\ *adj*
**mi-cro-read-er** \ˈmī-krō-ˌrē-dər\ *n* (1949) : an apparatus that gives an enlarged image of a microphotograph esp. for reading
**mi-cro-re-pro-duc-tion** \ˌmī-krō-ˌrē-prə-ˈdək-shən\ *n* (1938) : the reproduction of written or printed matter in microform; *also* : an item so reproduced
**mi-cro-scale** \ˈmī-krō-ˌskāl\ *n* (1931) : a very small scale
**mi-cro-scope** \ˈmī-krə-ˌskōp\ *n* [NL *microscopium*, fr. *micr-* + *-scopium* -scope] (1654) **1** : an optical instrument consisting of a lens or combination of lenses for making enlarged images of minute objects; *esp* : COMPOUND MICROSCOPE **2** : an instrument using radiations other than light or using vibrations for making enlarged images of minute objects ⟨acoustic ~⟩
**mi-cro-scop-ic** \ˌmī-krə-ˈskä-pik\ *or* **mi-cro-scop-i-cal** \-pi-kəl\ *adj* (1732) **1** : resembling a microscope esp. in perception **2 a** : invisible or indistinguishable without the use of a microscope **b** : very small or fine or precise **3** : of, relating to, or conducted with the microscope or microscopy — **mi-cro-scop-i-cal-ly** \-pi-k(ə-)lē\ *adv*
**mi-cros-co-py** \ˌmī-ˈkräs-kə-pē\ *n* (ca. 1665) : the use of or investigation with the microscope — **mi-cros-co-pist** \-pist\ *n*
**mi-cro-sec-ond** \ˈmī-krō-ˌse-kənd, -ˌkänt\ *n* [ISV] (1906) : one millionth of a second
**mi-cro-seism** \ˈmī-krə-ˌsī-zəm\ *n* [ISV *micr-* + Gk *seismos* earthquake] (1887) : a feeble rhythmically and persistently recurring earth tremor — **mi-cro-seis-mic** \ˌmī-krə-ˈsīz-mik, -ˈsīs-\ *adj* — **mi-cro-seis-mic-i-ty** \-sīz-ˈmi-sə-tē, -sis-\ *n*
**mi-cro-some** \ˈmī-krə-ˌsōm\ *n* [G *Mikrosom*, fr. *mikr-* micr- + *-som* -some] (1885) **1** : any of various minute cellular structures (as a ribosome) **2** : a particle in a particulate fraction that is obtained by heavy centrifugation of broken cells and consists of various amounts of ribosomes, fragmented endoplasmic reticulum, and mitochondrial cristae — **mi-cro-so-mal** \ˌmī-krə-ˈsō-məl\ *adj*
**mi-cro-spec-tro-pho-tom-e-ter** \ˌmī-krə-ˌspek-trə-fō-ˈtä-mə-tər\ *n* (1949) : a spectrophotometer adapted to the examination of light transmitted by a very small specimen (as a single organic cell) — **mi-cro-spec-tro-pho-to-met-ric** \-ˌfō-tə-ˈme-trik\ *adj* — **mi-cro-spectro-pho-tom-e-try** \-fō-ˈtä-mə-trē\ *n*
**mi-cro-sphere** \ˈmī-krə-ˌsfir\ *n* (1894) : a minute sphere — **mi-cro-spher-i-cal** \ˌmī-krə-ˈsfir-i-kəl, -ˈsfer-\ *adj*
**mi-cro-spo-ran-gi-um** \ˌmī-krō-spə-ˈran-jē-əm\ *n* [NL] (1881) : a sporangium that develops only microspores — **mi-cro-spo-ran-gi-ate** \-jē-ət\ *adj*
**mi-cro-spore** \ˈmī-krə-ˌspōr, -ˌspȯr\ *n* [ISV] (1858) : any of the spores in heterosporous plants that give rise to male gametophytes and are generally smaller than the megaspore — **mi-cro-spo-rous** \ˌmī-krə-ˈspōr-əs, -ˈspȯr-; mī-ˈkräs-pə-rəs\ *adj*
**mi-cro-spo-ro-cyte** \-ˈspōr-ə-ˌsīt, -ˈspȯr-\ *n* (1940) : a microspore mother cell
**mi-cro-spo-ro-gen-e-sis** \ˌmī-krə-ˌspōr-ə-ˈje-nə-səs, -ˌspȯr-\ *n* [NL] (1921) : the formation and maturation of microspores
**mi-cro-spo-ro-phyll** \-ˌfil\ *n* (ca. 1890) : a sporophyll that develops only microsporangia
**mi-cro-state** \ˈmī-krō-ˌstāt\ *n* (1962) : a nation that is extremely small in area and population
**mi-cro-struc-ture** \ˈmī-krō-ˌstrək-chər\ *n* [ISV] (1885) : the microscopic structure of a material (as a mineral or a biological cell) — **mi-cro-struc-tur-al** \ˌmī-krō-ˈstrək-chə-rəl, -ˈstrək-shrəl\ *adj*
**mi-cro-sur-gery** \ˌmī-krō-ˈsərj-rē, -ˈsər-jə-\ *n* (1926) : minute dissection or manipulation (as by a micromanipulator or laser beam) of living structures or tissue — **mi-cro-sur-gi-cal** \-ˈsər-ji-kəl\ *adj*
**mi-cro-switch** \-ˌswich\ *n* (1940) : a very small switch that is sensitive to minute motions and is used esp. in automatic devices
**mi-cro-tech-nique** \ˌmī-krō-tek-ˈnēk\ *also* **mi-cro-tech-nic** \-ˈtek-nik, -tek-ˈnēk\ *n* [ISV] (1892) : any of various methods of handling and preparing material for microscopic observation and study
**mi-cro-tome** \ˈmī-krə-ˌtōm\ *n* [ISV] (1856) : an instrument for cutting sections (as of organic tissues) for microscopic examination
**mi-cro-tone** \ˈmī-krə-ˌtōn\ *n* (1920) : a musical interval smaller than a halftone — **mi-cro-ton-al** \ˌmī-krə-ˈtō-nᵊl\ *adj* — **mi-cro-to-nal-i-ty** \-tō-ˈna-lə-tē\ *n* — **mi-cro-ton-al-ly** \-ˈtō-nᵊl-ē\ *adv*
**mi-cro-tu-bule** \ˌmī-krō-ˈtü-(ˌ)byü(ə)l, -ˈtyü-\ *n* (1961) : any of the minute tubules in eukaryotic cytoplasm that are composed of the protein tubulin and form an important component of the cytoskeleton, mitotic spindle, cilia, and flagella — **mi-cro-tu-bu-lar** \-byə-lər\ *adj*
**mi-cro-vas-cu-lar** \-ˈvas-kyə-lər\ *adj* (1959) : of, relating to, or constituting the part of the circulatory system made up of minute vessels (as venules or capillaries) that average less than 0.3 millimeters in diameter — **mi-cro-vas-cu-la-ture** \-lə-ˌchůr, -ˌtyůr, -ˌtůr\ *n*
**mi-cro-vil-lus** \-ˈvi-ləs\ *n* [NL] (1953) : a microscopic projection of tissue, cell, or cell organelle; *esp* : any of the fingerlike outward projections of some cell surfaces — **mi-cro-vil-lar** \-ˈvi-lər\ *adj* — **mi-cro-vil-lous** \-ˈvi-ləs\ *adj*
**mi-cro-volt** \ˈmī-krə-ˌvōlt\ *n* (1868) : one millionth of a volt
**mi-cro-watt** \-ˌwät\ *n* (ca. 1909) : one millionth of a watt
**¹mi-cro-wave** \-ˌwāv\ *n, often attrib* (1931) **1** : a comparatively short electromagnetic wave; *esp* : one between about 1 millimeter and 1 meter in wavelength **2** : MICROWAVE OVEN
**²microwave** *vt* (1973) : to cook or heat in a microwave oven — **mi-**
**cro-wav-able** *or* **mi-cro-wave-able** \ˌmī-krə-ˈwā-və-bəl\ *adj*
**microwave oven** *n* (1963) : an oven in which food is cooked by the heat produced by the absorption of microwave energy by water molecules in the food
**mi-cro-world** \-ˌwər(-ə)ld\ *n* (1955) : a small universe; *specif* : the natural universe observed at the microscopic or submicroscopic level
**mic-tu-rate** \ˈmik-chə-ˌrāt, ˈmik-tə-\ *vi* **-rat-ed; -rat-ing** [L *micturire*, to desire to urinate, fr. *meiere* to urinate; akin to OE *migan* to urinate; Gk *omeichein*] (1842) : URINATE — **mic-tu-ri-tion** \ˌmik-chə-ˈri-shən, ˌmik-tə-\ *n*
**¹mid** \ˈmid\ *adj* [ME, fr. OE *midde*; akin to OHG *mitti* middle, L *medius*, Gk *mesos*] (bef. 12c) **1** : being the part in the middle or midst ⟨in ~ ocean⟩ — often used in combination ⟨*mid*-August⟩ **2** : occupying a middle position ⟨the ~ finger⟩ **3** *of a vowel* : articulated with the arch of the tongue midway between its highest and its lowest elevation — **mid** *adv*
**²mid** *prep* (1808) : AMID
**mid-air** \ˈmid-ˈar, -ˈer\ *n* (1667) : a point or region in the air not immediately adjacent to the ground ⟨planes collided in ~⟩
**Mi-das** \ˈmī-dəs\ *n* [L, fr. Gk] : a legendary Phrygian king who is given the power of turning everything he touches to gold
**Midas touch** *n* (1883) : an uncanny ability for making money in every venture
**mid-brain** \ˈmid-ˌbrān\ *n* (1875) : the middle of the three primary divisions of the developing vertebrate brain or the corresponding part of the adult brain — called also *mesencephalon*; see BRAIN illustration
**mid-course** \-ˈkōrs, -ˈkȯrs\ *adj* (ca. 1956) : being or occurring in the middle part of a course (as of a spacecraft) ⟨a ~ correction⟩
**mid-day** \ˈmid-ˌdā, -ˈdə\ *n, often attrib* (bef. 12c) : the middle of the day
**mid-den** \ˈmi-dᵊn\ *n* [ME *midding*; of Scand origin; akin to ON *mykidung* & ON *dyngja* manure pile — more at DUNG] (14c) **1** : DUNGHILL **2 a** : a refuse heap; *esp* : KITCHEN MIDDEN **b** : a small pile (as of seeds, bones, or leaves) gathered by a rodent (as a pack rat)
**¹mid-dle** \ˈmi-dᵊl\ *adj* [ME *middel*, fr. OE; akin to OE *midde*] (bef. 12c) **1** : equally distant from the extremes : MEDIAL, CENTRAL ⟨the ~ house in the row⟩ **2** : being at neither extreme : INTERMEDIATE **3** *cap* **a** : constituting a division intermediate between those prior and later or upper and lower ⟨*Middle* Paleozoic⟩ **b** : constituting a period of a language or literature intermediate between one called *Old* and one called *New* or *Modern* ⟨*Middle* Dutch⟩ **4** *of a verb form or voice* : typically asserting that a person or thing both performs and is affected by the action represented
**²middle** *n* (bef. 12c) **1** : a middle part, point, or position **2** : the central portion of the human body : WAIST **3** : the position of being among or in the midst of something **4** : something intermediate between extremes : MEAN **5** : the center of an offensive or defensive formation; *esp* : the area between the second baseman and the shortstop
**middle age** *n* (14c) : the period of life from about 40 to about 60 — **mid-dle-aged** \ˌmi-dᵊl-ˈājd\ *adj* — **mid-dle-ag-er** \-ˈā-jər\ *n*
**Middle Ages** *n pl* (1616) : the period of European history from about A.D. 500 to about 1500
**Middle America** *n* (1898) **1** : the region of the western hemisphere including Mexico, Central America, often the West Indies, and sometimes Colombia and Venezuela **2** : the midwestern section of the U.S. **3** : the middle-class segment of the U.S. population; *esp* : the traditional or conservative element of the middle class — **middle-American** *adj* — **Middle American** *n*
**mid-dle-brow** \ˈmi-dᵊl-ˌbraů\ *n* (1925) : a person who is moderately but not highly cultivated — **middlebrow** *adj*
**middle C** *n* (1840) : the note designated by the first ledger line below the treble staff and the first above the bass staff
**mid-dle-class** \ˌmi-dᵊl-ˈklas\ *adj* (1836) : of or relating to the middle class; *esp* : characterized by a high material standard of living, sexual morality, and respect for property — **mid-dle-class-ness** \-nəs\ *n*
**middle class** *n* (1766) : a class occupying a position between the upper class and the lower class; *esp* : a fluid heterogeneous socioeconomic grouping composed principally of business and professional people, bureaucrats, and some farmers and skilled workers sharing common social characteristics and values
**middle distance** *n* (1813) **1** : a part of a pictorial representation or scene between the foreground and the background **2** : any footrace distance usu. from 800 to 1500 meters or from 880 yards to one mile
**Middle Dutch** *n* (ca. 1959) : the Dutch language in use from about 1100 to about 1500 — see INDO-EUROPEAN LANGUAGES table
**middle ear** *n* (1852) : a small membrane-lined cavity that is separated from the outer ear by the eardrum and that transmits sound waves from the eardrum to the partition between the middle and inner ears through a chain of tiny bones
**Middle English** *n* (1830) : the English in use from the 12th to 15th centuries — see INDO-EUROPEAN LANGUAGES table
**middle finger** *n* (bef. 12c) : the midmost of the five digits of the hand
**Middle French** *n* (1889) : the French in use from the 14th to 16th centuries — see INDO-EUROPEAN LANGUAGES table
**middle game** *n* (1894) : the middle phase of a board game; *specif* : the part of a chess game after the pieces have been developed when players attempt to gain and exploit positional and material superiority — compare ENDGAME, OPENING
**Middle Greek** *n* (1889) : the Greek language used in the 7th to 15th centuries
**middle ground** *n* (1801) **1** : a standpoint midway between extremes **2** : MIDDLE DISTANCE 1
**Middle High German** *n* (1889) : the High German in use from about 1100 to 1500 — see INDO-EUROPEAN LANGUAGES table

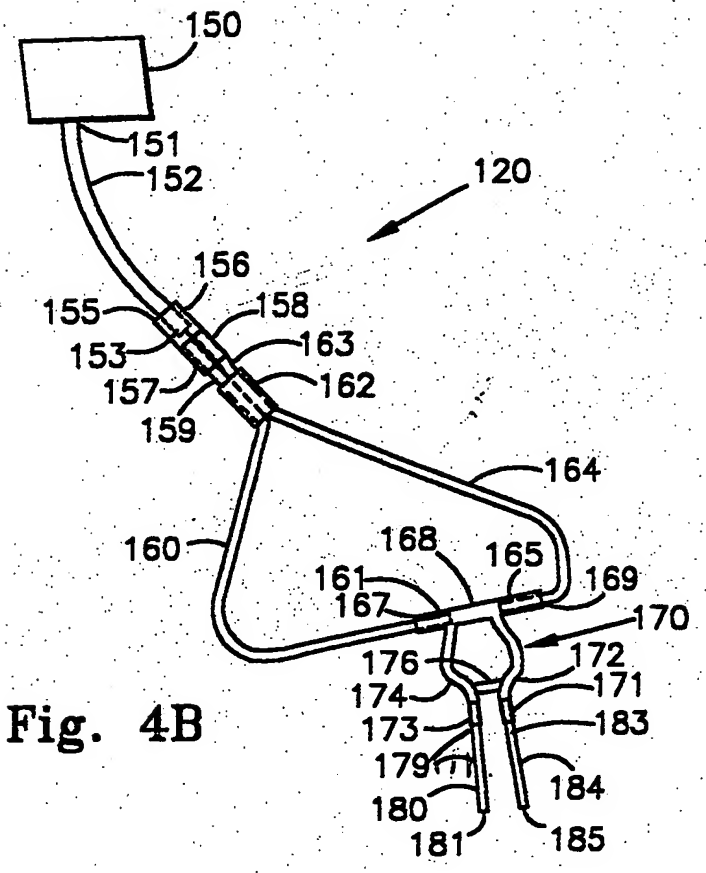



Fig. 4B

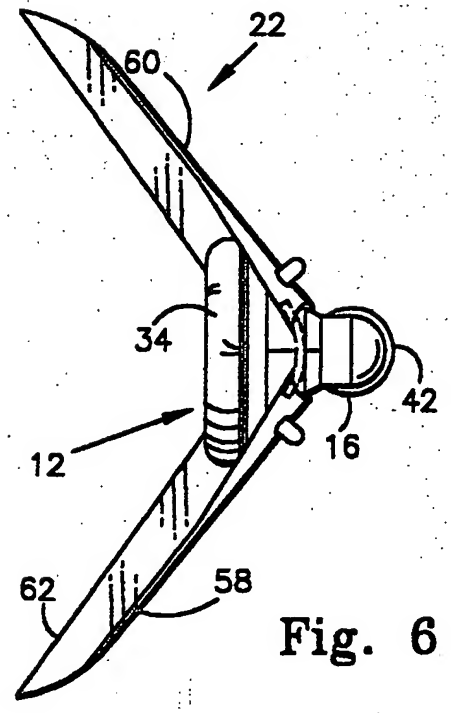



Fig. 6

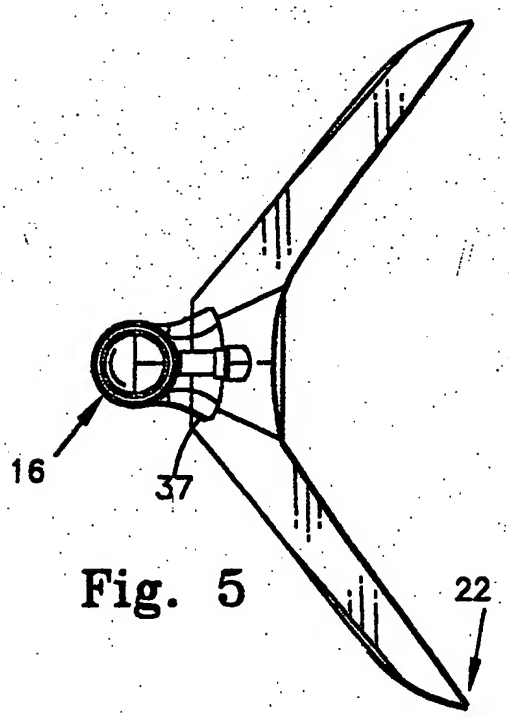



Fig. 5